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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,203	01/03/2006	David John Miller	GJE-7224	6476

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EXAMINER	
NWAONICHA, CHUKWUMA O	
ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,203	MILLER ET AL.	
	Examiner	Art Unit	
	Chukwuma O. Nwaonicha	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-20 and 22* is/are allowed.

6)☒ Claim(s) *23-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/17/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Current Status

1. Claims 1-20 and 22-30 are pending in the application.

2. This action is responsive to Applicants' amendment of 3 January 2006.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Claim Objection

Claim 23 is objected for depending on claim 30. Claim 23 should depend on any of the preceding claims 1-20 or 22. Clarification is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for "treatment or prevention of endometriosis, uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic

malfunction and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" as claimed.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The standard for determining whether the specification meets the enablement requirement is whether experimentation needed to practice the invention is undue or unreasonable. Accordingly, even though the forgoing statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. See M.P.E.P. § 2164.

In the instant case, the claims cover "treatment or prevention of endometriosis, uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic malfunction and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" with the compound of formula I or II is speculative. Based on the above standards, the disclosure must contained sufficient information to enable one skilled in the pertinent art to use this invention without undue experimentation. See M.P.E.P. 2164.01. Given the scope of the claims, it does not, because "treatment or prevention of endometriosis,

uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic malfunction and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" with the compound of formula I or II is speculative.

The Examiner understands that there is no requirement that the specification disclose every possible embodiment if there is sufficient guidance given by knowledge in the art (See M.P.E.P. § 2164.05(a)). However, the instant case goes beyond what is known in the art, because the specification does not offer any guidance on how one of ordinary skill would go about practicing the invention from the claim to "treatment or prevention of endometriosis, uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic malfunction and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" with the compound of formula I or II.

Here, the requirement for enablement is not met since the claims go far beyond the enabling disclosure. Based on the forgoing, **claims 23-30** are *prima facie* non-enabled for their full scope.

With regard to rejection under 35 U. S. C. 112, first paragraph, the following factors have been carefully considered (***In re* Wands**, 8 USPQ2d 1400; CAFC, 1988):

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

(1) **Nature of the invention.** As indicated above, the invention is drawn to "treatment or prevention of endometriosis, uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic malfunction and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" with the compound of formula I or II.

(2) **Breadth of the Claims.** The claims are extremely broad. In particular, **claims 23-30** that read on specifically "treatment or prevention of endometriosis, uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic malfunction

and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" with the compound of formula I or II.

Applicants have failed to exactly show how to "treatment or prevention of endometriosis, uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic malfunction and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" with the compound of formula I or II.

(3) **State of the Prior Art.** While the following diseases may be treated, there is no known "prevention of endometriosis, uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic malfunction and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" with the compound of formula I or II. The prior art discloses method for treating related diseases with Non-peptide GnRH (US 7,101,878).

(4) **Unpredictability of the Art.** The instant case is drawn to "treatment or prevention of endometriosis, uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual

syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic malfunction and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" with the compound of formula I or II. "Treatment or prevention of endometriosis, uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic malfunction and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" with the compound of formula I or II is speculative. Applicants' claim to" treatment or prevention of endometriosis, uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic malfunction and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" with the compound of formula I or II is doubtful due to the wide variety of causative factors which would have different method of treatment and requires objective proof. In such a speculative field, more enablement by way of specific examples is necessary in order to establish the utility of a genus. In re Fisher, 166 U.S.P.Q. 18.

(5) **Amount of Guidance Provided.** Applicants have provided no guidance for using the claimed method to "treatment or prevention of endometriosis, uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic malfunction and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" with the compound of formula I or II. For instance, applicants state that an effective amount of the compound of formula I or II should be administered to a patient. However, when considering that the claim read on "treatment or prevention of endometriosis, uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic malfunction and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" with the compound of formula I or II it becomes critical to know how long does one administers the said compound to "prevent or treatment" of theses diseases. This is critical to the practice of the invention and therefore should adequately be disclosed.

(6) **Presence or Absence of Working Examples.** There are no examples of "treatment or prevention of endometriosis, uterine myoma, an ovarian disease, a

mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic malfunction and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" with the compound of formula I or II disclosed. Applicants only discourse various formulations and mode of application of the pharmaceutical composition.

(7) **Ordinary Skill in the Art.** The ordinary skill artisan would not be able to practice the claimed invention with the current disclosure. This is a new field with no known success for the "treatment or prevention of endometriosis, uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic malfunction and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" with the compound of formula I or II.

(8) **Amount of Experimentation Necessary.** A great deal of experimentation is required. In lieu of the fact that no animal models exist which can reasonably suggest successful "treatment or prevention of endometriosis, uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign

prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic malfunction and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" with the compound of formula I or II, it will be necessary for an ordinary skilled artisan to have clinical data in order to practice the claimed invention.

Thus, it can safely be concluded that the instant disclosure fails to provide an enabling disclosure for "treatment or prevention of endometriosis, uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, Alzheimer's disease, HIV infection or AIDS, a disease caused by thymic malfunction and cancer, multiple sclerosis, rheumatoid arthritis or type 1 diabetes" with the compound of formula I or II.

Allowed Claims

Claims 1-20 and 22 are allowable over the prior art of record.

Reason For Allowance

The following is an examiner's statement of reasons for allowance: A search of the prior art failed to uncover any reference that anticipates or renders obvious a compound of general formula I or II as claimed by applicants.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chukwuma O. Nwaonicha whose telephone number is

571-272-2908. The examiner can normally be reached on Monday thru Friday, 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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